K001808

AUG 4 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: pro med instruments GmbH
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Contact Person: Edgar Schuele, President

Date Prepared: May 30, 2000

Classification Name: Neurological Surgical Device

Common/Usual Name: Neurosurgical Head Holder (skull clamp)

Proprietary Name: DORO® Headrest System

Predicate Device: Ohio Medical Mayfield A-2000 Skull Clamp (K932807)

Device Description: The DORO® Headrest System is a device used as a support during head and neck surgery. It is composed of several components. These components are: 1. the adjustable base unit, 2. the skull clamp, 3. the swivel adaptor and 4. the reusable and disposable skull pins. It is suitable for adults and children.

The DORO® System uses a three-point fixation of the head during surgery in the prone, supine, lateral and sitting positions. The double clamping of the adjustable base unit provides simultaneous fixation of the lateral and vertical positions. The crossbar is used for connection to the side rails of standard operating tables for fixation in a sitting position. The Swivel Adaptor is used with the base unit to provide 360 degree rotation.

The Headrest System, except for the disposable skull pins, is sold non-sterile. The base unit, swivel adaptor and skull clamp are intended to be cleaned by the user between uses and the reusable pins are to be sterilized before use. The disposable pins are provided sterile.

The components of the Headrest System are made of the following materials: Skull clamp is made of cast aluminum, stainless steel and Teflon. The reusable skull pins are made

of stainless steel and Teflon, the swivel adaptor is made of cast aluminum, stainless and Teflon, the base unit is made of cast aluminum, stainless steel and Teflon.

The Headrest System also can be used with accessories such as a horseshoe headrest with elastic pads for adults, headrest supports with one or two elastic pads, single pin holders, dual pin holders for adults, dual pin holders for children, a multi-purpose skull clamp with six pin fixation or with three elastic pads.

The Headrest can also be used with an additional accessory which allows for use as a support and retraction device during neurosurgical procedures where retraction of the brain tissue and handrest are needed. The Halo Retractor accessory is also made of cast aluminum, stainless steel and Teflon.

The DORO® Headrest System can also be used with an optional Halo Retractor System as an arm rest and tissue retractor.

Intended Use:

The DORO® Headrest System is used as a support mechanism for head and neck surgery.

The DORO® Halo Retractor System is used as a head and neck support during neurosurgical procedures where retraction of tissue is also required.

Materials:

Materials which do not contact body tissues and are used on skin surfaces only are made of cast aluminum, stainless steel and Teflon. The skull pins and Halo retractor parts that come in contact with tissue are made of stainless steel.

Substantial Equivalence Rationale:

The DORO® Headrest System is used a head and neck support to stabilize a patient's head during neurosurgical operative procedures. This is the same use as the Ohio Medical Mayfield A-2000 Skull Clamp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Pro-Med Instruments GmbH
c/o Ms. Anita Thibeault
Anita Thibeault & Associates
9070 Bluffview Trace
Roswell, Georgia 30076

Re: K001808
Trade Name: Doro Headrest System
Regulatory Class: II
Product Code: HBL
Dated: May 15, 2000
Received: June 15, 2000

Dear Ms. Thibeault:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001808

Device Name: DORO® HEADREST SYSTEM

Indications For Use:

The DORO® Headrest System is intended as a neck and head support to stabilize the patient's head during neurosurgical operative procedures. The DORO® Halo Retractor Accessory is intended to be used as an arm rest and tissue retractor during neurosurgical operative procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna P. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
(Division Sign-Off) Number K001808

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)